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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,181	04/26/2001	Chris Sikorski	CER-298	9166

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EXAMINER	
WHITE, EVERETT NMN	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/843,181	SIKORSKI ET AL.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 26, 2004 has been entered.

2. The amendment filed April 26, 2004 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Claims 1-6 and 11-19 have been canceled.
(B) Claims 7 have been amended.
(C) Comments regarding Office Action have been provided drawn to:
    (i) 103(a) rejection, rendered moot by new ground of rejection over newly cited US Patent.

3. Claims 7-10 are pending in the case.

4. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 7, lines 8-11, the passage "recovering a dried, porous, flake-shaped, uncomplexed agglomerated modified cyclodextrin product have a particle distribution of about 90% or more by weight of said product less than or equal to 200 microns," needs to be stated more clearly what feature the claim is referring to or sentence punctuations should be added in the passage to clarify the claimed language. Claims 8-10 are also rejected since these claims depend from Claim 7.

In Claim 7, in the absence of the specific modification to the chemical core claimed (cyclodextrin product) or distinct language to describe the structural modifications or the chemical names of the modified cyclodextrin of this invention, the identity of said modified cyclodextrin would be difficult to describe and the metes and bounds of said modified cyclodextrin that Applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims. Claims 9 and 10 are also rejected for the same reason since these claims depend from Claim 7.

Claim Rejections - 35 USC § 103

6. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al (US Patent No. 6,153,746) in view of Walsh (US Patent No. 5,980,971) or Giacobello (US Patent No. 4,127,944) or Fuertes et al (US Patent No. 5,756,484).

Applicants claim a process for making a dried porous, flake-shaped, uncomplexed agglomerated modified cyclodextrin product comprising drying an aqueous solution of uncomplexed modified cyclodextrin on a double-drum dryer, wherein the aqueous solution has a solids content of between about 5 to about 70% by weight; and recovering a dried porous, flake-shaped, uncomplexed agglomerated modified cyclodextrin product having a particle distribution of about 90% or more by weight, the particles having a particle size less than or equal to 200 microns, about 50% or more by weight of said product having particles greater than or equal to 20 microns, and wherein said product has a dissolution time in water less than about 5 minutes at 75°F and 10% solids. Additional limitations in the dependent claims include hydroxypropylated beta-cyclodextrin selected as the cyclodextrin; specific revolutions per minute of the rotation of the drums on the drum-dryer; and a specific pressure of the heated drums.

The Shah et al patent discloses sulfoalkyl ether cyclodextrins that are suitable for use as clathrating agents with drugs to provide complexes, which are useful in parenteral and other pharmaceutical formulation. The Shah et al patent provides a solution of sulfoalkyl ether cyclodextrin that can be isolated by a suitable drying

technique that may be selected as vacuum drum drying (see column 3, lines 23-26). The sulfoalkyl ether cyclodextrin embraces the modified cyclodextrin product of the instant claims. See column 1, line 51 of the Shah et al patent whereby hydroxypropyl-β-cyclodextrin is disclosed as a well known cyclodextrin for forming inclusion complexes with hydrophobic molecules, which embraces the hydroxypropylated beta-cyclodextrin set forth in Claim 8. The examples in the shah et al patent set forth modified cyclodextrin products comprising solids content that falls within the claimed range wherein the aqueous solution of the uncomplexed modified cyclodextrin has a solids content of between about 5 to about 70% by weight. The instant claims differ from the Shah et al patent by claiming that the cyclodextrin is agglomerated and comprises particle sizes of less than or equal to about 200 microns.

The Walsh patent is cited to further characterize the operation of drum dryers, which is well known in the art. See column 6, first paragraph of the Walsh patent whereby a preferred method of drying products is rotating drum dryers. The paragraph further discloses the drum dryers being heated by steam from 10 to 150 pounds of pressure per square inch, which covers part of the pressure set forth in the instant claims. The paragraph further explains that the thickness of the product can be varied by changing the settings of the drum dryer gap between the rolls, whereby a preferred product is a material of 0.0001 to 0.25 inches in thickness, which shows that it is within the skill of an artisan to obtain particle size of the particles indicated in the instant claims. The Walsh patent discloses that the product is dried to a moisture content of 5-12% (see column 6, lines 16 and 17), which suggests the particle distribution of 90% or more recited in instant Claim 7.

The Giacobello patent teaches that the use of a drum dryer to improve the agglomeration of a dried product is well known in the art. See the text at column 10, 3rd paragraph of the Giacebello patent whereby a variation in the drying method is disclosed whereby a drum dryer can be enclosed in a vacuum chamber where the actual drying is carried out under reduced pressures. Giacobello discloses "that such variation will ordinarily hasten the drying process and in some instances lead to still further improved agglomeration of the dried product with consequent production of less

fines while maintaining high absorbent properties". It is noted that the Shah patent does discloses the use of "vacuum drum drying" to produce the modified cyclodextrin product thereof (see column 3, line 26 of the Shah patent), which suggests an agglomerated product in view of the teachings of the Giacebello patent.

Applicants further amended the Claim 7 to set forth that the dissolution time of the product in water is less than about 5 minutes at 75° F and 10% solids. The Fuertes et al patent shows that modified cyclodextrins such as hydroxypropyl-β-cyclodextrin possessing such a property is well known in the art. See the table in column 8 of the Fuertes et al patent wherein a hydroxypropyl-β-cyclodextrin composition having dissolution time in aqueous medium is below 5 minutes. The composition at No. 3 in the table appears to be the closest in particle size to the cyclodextrin product recited in the instant claims, which sets forth particles size of the product of 0% being less than 10 μ, 1% of the particles being less than 100 μ, and 11% of the particles being greater than 315 μ, wherein the dissolution time at 21° C in a 10% solution is 35 seconds.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the drum drying process conditions for preparing a dried modified cyclodextrin using the combination of the Shah et al and Walsh patents with a process condition whereby the drum dryer is enclosed in a vacuum chamber in view of the recognition in the art, as evidenced by the Giacobello patent, that such process condition allows for further improvement of agglomeration of dry products with production of less fines while maintaining high absorbent properties. The Fuertes et al patent shows that the dissolution time of less than 5 minutes is an inherent property of certain modified cyclodextrins which does not suggest patentability of the instantly claimed process for making a dried, porous, flake-shaped, uncomplexed agglomerated modified cyclodextrin product.

Summary

7. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

8. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E.White

Elli Peselev
Primary Examiner
Technology Center 1600